EC CERTIFICATE

Number: 2113812CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

B. Braun Medical AG

Seesatz 17
6204 Sempach
Switzerland

For the product category(ies)

Medical devices for Wound Bed Preparation

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2113812CN, initially dated 12 February 2008
Addendum, initially dated 12 February 2008

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024
Issued for the first time: 12 February 2008
Reissued: 3 December 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

Digitally signed by Sarco Alexandru
Date: 2024.04.10 11:26:23 EEST
Reason: MoldSign Signature
Location: Moldova

DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 2113812CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Medical devices for Wound Bed Preparation

Issued to:

B. Braun Medical AG
Seesatz 17
6204 Sempach
Switzerland

This certificate covers the following product(s):

- Prontosan Wound Gel (Class III)
- Prontosan Wound Irrigation Solution (Class III)
- Prontosan Wound Gel X (Class III)
  (for cleansing, moisturizing and decontamination of acute wounds, chronic wounds, thermal wounds, chemical and radiation-induced wounds)
- Prontosan acute Wound Gel (Class III)
  (for cleansing and moistening of superficial wounds, including superficial burns)
- Prontosan Wound Spray (Class III)
  (for cleansing, irrigation and moistening of superficial acute and chronic wounds including superficial burns)
- LavaSurge Wound Irrigation Solution (Class IIb)
  (for cleansing and irrigation of acute and chronic non-infected and infected wounds; for intraoperative wound cleansing and irrigation)

Initial date: 12 February 2008
Revision date: 26 January 2017

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344